

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Jacques Marie Rene JAN HUYGHE et al.

Group Art Unit: 3775

Application No.: 10/564,518

Examiner: A. YANG

Filed: March 1, 2007

Docket No.: 203858

For: PROSTHESIS MADE OF A FIBRE-REINFORCED HYDROGEL, METHOD OF
MANUFACTURING THE PROSTHESIS AND USE THEREOF

**DECLARATION OF JACQUES MARIE RENE JAN HUYGHE
PURSUANT TO 37 C.F.R. §1.132**

Jacques Marie Rene Jan Huyghe declares and says:

1. My principal place of business is Eindhoven, The Netherlands. I make this Declaration on behalf of the Technische Universiteit Eindhoven, owner by assignment of the above-referenced patent application.

2. I am the named inventor in the above-referenced patent application and I am named inventor on approximately two United States patents in the field of hydrogel-type prosthesis.

3. I am currently an associated professor at the Eindhoven University of Technology, The Netherlands. I have a Master Degree in Civil Engineering from the University of Ghent, Belgium. I have a Ph.D. from the Eindhoven University of Technology from 1986. After an assistant-professorship at the Universiteit Maastricht, The Netherlands, I was nominated as a fellow of the Royal Netherlands Academy of Arts and Sciences from 1996 to 2001.

4. I have over 30 years experience in the field of biomechanics, including 15 years in the sub-field of hydro-gel prosthesis. My current research is focused on porous

media mechanics of swelling materials with applications in the field of biomechanics, prosthesis design and petroleum engineering. Moreover, I am a steering member of the Poromechanics Committee of the American Society of Civil Engineer. I am an associate editor of the J. Biomech. Engng. Of the American Society of Mechanical Engineers, the journal Biorheology and the journal Transport in Porous Media.

5. I have again reviewed the above-referenced patent application ("application") to again review the application as published on August 2, 2007, claims 1-11, 21-33 and 37 currently pending in this application and as currently amended pursuant to the Amendment, submitted herewith and to which this Declaration is appended, and five prior art patents, cited by the United States Patent and Trademark Office ("PTO") during the prosecution of this application. The five prior patents are: U.S. Patent No. 5,458,643 ("Oka"), U.S. Patent No. 7,008,635 ("Coury"), U.S. Patent No. 6,264,695 ("Stoy"), U.S. Patent No. 3,867,728 ("Stubstad") and U.S. Patent No. 5,047,055 ("Bao").

6. I have arrived at certain factual conclusions regarding the correctness of the conclusions reached by the PTO, as set out in an Office Action, mailed on June 15, 2011. In arriving at my conclusions, as set out below, I have relied on my experience in the same field of technology as to which the application relates, my understanding of the teachings of the Oka, Coury, Stoy, Substad and Bao references, the PTO's explanation for the rejection of the claims presently pending in the application, and my understanding of the standard by which "anticipation" and "obviousness" of an invention as set out in claims is determined.

7. I am informed that anticipation is based on a standard that requires a cited prior art reference to disclose each and every element of a claim; if a prior art reference does not disclose a claimed feature, it cannot anticipate the claim.

8. I am informed that obviousness is based on a standard that includes at least the following factors: the scope and content of the prior art; differences between the prior art and the claims at issue; and the level of ordinary skill in the pertinent art. I am also informed that

secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etc., can be utilized to give meaning to the circumstances surrounding the origin of the subject matter sought to be patented.

9. I have also been made aware that evaluating obviousness, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

10. I am also advised that rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

11. I am also advised that a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered and claim discoveries almost of necessity will be combinations of what, in some sense, is already known.

12. I have taken these factors fully into account in my review of the materials described above and in the factual conclusions I have drawn from those materials.

13. One of ordinary skill in the art of biomechanics will typically have at least a competent level of experience as a scientist-engineer in the area of prosthesis design, or other specialty that requires the background of biomechanics. My evaluation takes into account this standard of ordinary skill.

14. From my review of the materials relating to the application, I understand that the PTO has rejected claims directed to a prosthesis and method of using the same disclosed in the application on the grounds that claims Claims 1-11, 21, 24-27 and 29-33 are unpatentable over Oka in view of Coury, Stoy and Stubstad, and that claims 22 and 23 are unpatentable over these references in view of Bao. Office Action of June 15, 2011 at 2-6. In particular, column 9:48-51 of Coury is cited as disclosing a "hydrogel containing chopped fibres," as recited in claim 1.

15. I understand the PTO's position to be that while Oka fails to disclose a hydrogel having chopped fibres, Coury teaches "using hydrogels to form intervertebral disc implants and that fibers can be added to the hydrogel to improve their toughness under load and shear." The PTO concludes based on its understanding of the teachings of Oka, Coury and the other cited references would have been obvious to combine in a manner that produces the claimed prosthesis.

16. The PTO's conclusions are not valid. The cited portions of Coury do not disclose "chopped fibers," but only "fibers." Coury discloses an invention using "the key attributes of the formed hydrogel are low swelling at high proportions of solids..." See Coury at col. 3:8-9. The differences and advantages of using chopped fibers specifically, particularly when combined with a hydrogel having negatively charged groups (*i.e.*, highly swellable), are that, unlike claims by Coury, highly swellable hydrogels which are explicitly excluded from Coury (col. 3:31-36) can still have high toughness and strength. The restraining of the swelling in Coury is intrinsic to the use of low swellable material, while in our patent, the restraining of the swelling lies in the use of a flexible, swelling part in combination with a less flexible part, which is an entirely different design, much closer to the design of the natural disc, which contains highly swellable ionized groups (proteoglycans) the swelling of which is restrained by a collagen network physically distinct from the proteoglycan gel. Coury actually teaches away from using highly swellable ionized gels

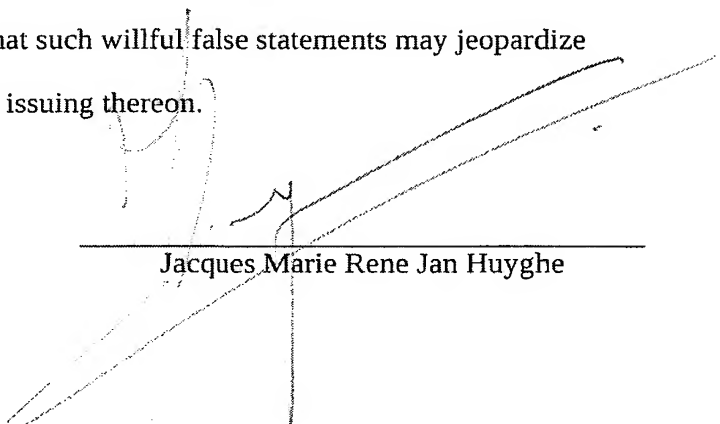
because they are "highly 'elastic' (compliant) and correspondingly do not resist stress well." Col. 3:34-36. None of Oka, Coury or any other cited prior art reference discloses how these highly swellable materials can be arranged such that they would be suitable for use in a prosthesis. This only source for this teaching in the record is the instant application itself.

17. The PTO's rejections also appear to omit a number of features of the dependent claims, including (but not limited to) the features that the hydrogel "contains at least 5% fibres" (claim 10), that the "volume of the prosthesis is reduced by immersing it in a hypertonic salt bath" (claim 23), that the angle at which the fibres are arranged with respect to the axis of rotation "varies from 5° to 90°" (claim 25) or "from 45° to 60°" (claim 26), that the "fibres wound around the flexible portion are capable of absorbing hydrogel monomers" (claim 32) or that the hydrogel "is configured to absorb fluid by osmotic action when the hydrogel is at rest" (claim 37).

18. The undersigned declares further that all statements made herein on his own knowledge are true and that false statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

12-09-2011



Jacques Marie Rene Jan Huyghe